

TESTIMONY

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BEFORE

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FDA AND RELATED AGENCIES APPROPRIATIONS

SUBCOMMITTEE

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Introduction

Mr. Chairman and members of the Subcommittee, it is an honor to appear before you as Acting Commissioner of the Food and Drug Administration (FDA) to present the President's fiscal year 2007 budget request. I am joined today by Ms. Kathy Heuer, FDA's Chief Financial Officer and Associate Commissioner for Management, and Mr. Richard Turman, Deputy Assistant Secretary for Budget, Technology, and Finance of the Department of Health and Human Services (DHHS). I also have members of FDA's senior leadership with me at today's hearing.

Last September, President Bush selected me to lead an agency to which I appreciate, we, as Americans owe a great debt of gratitude. Millions of Americans go to sleep each night, secure in the knowledge that the food they ate and the medicines they gave their child were safe and effective. They do so, thanks to the thousands of dedicated professionals at FDA who work to assure the safety, efficacy, and security of drugs, vaccines and biological products, medical devices, our nation's food supply, and other consumer products.

This year, the Food and Drug Administration will celebrate its 100th birthday, marking a century as America's gold standard for safety and consumer protection. We began in 1906, when Congress passed and President Theodore Roosevelt signed the Food and Drugs Act. This statute entrusted the Bureau of Chemistry, an office in the U.S. Department of Agriculture, to implement the sweeping new law. The Bureau eventually became the FDA, an agency of the Department of Health and Human Services. As the first consumer protection agency in the United States, FDA has a distinguished record, established during its 100 years of service to the

American public.

Today, the products we regulate represent almost 25 percent of U.S. consumer spending and include 80 percent of our food supply and all human drugs, vaccines, medical devices, tissues for transplantation, equipment that emits radiation, cosmetics, and animal drugs and feed. FDA takes great pride in its heritage and accomplishments, promoting and protecting the health and well-being of all Americans.

I assure you that the precious resources you provide this agency in fiscal year 2007 will be used wisely and judiciously to ensure that we maintain this record of excellence, as well as work to respond to the growing challenges to advance the nation's public health in a new era of rapidly developing science and individualized medicine.

I want to thank the Subcommittee members for providing FDA with several key increases in the FY 2006 appropriation. The Subcommittee demonstrated its commitment to FDA's mission by providing increases for drug safety, the Critical Path Initiative, review of direct-to-consumer advertising, Food Defense, medical device review, and the FDA consolidation project at White Oak, Maryland. In addition to the amounts in the annual appropriations bill, I also want to express my thanks to Congress for the supplemental appropriation of \$20 million to contribute to our nation's preparedness for the threat of pandemic flu. FDA enters this appropriation cycle mindful of our responsibility and stewardship, and that all federal agencies must operate in an environment where our dollars must go to the greatest need.

FDA's 2007 President's Budget Request

In our FY 2007 budget, the Administration proposes a total program level for the FDA budget of \$1.95 billion, an increase of 3.8 percent above the FY 2006 amount. This includes \$1.54 billion in discretionary budget authority and \$402 million in current law user fees. Our budget also includes \$25.5 million for two new user fees. Our budget request maintains critically important core functions and demonstrates that our programs meet a firm test of accountability. At the same time, we are heeding the President's call to assure continued progress by fostering innovation and focusing on emerging priorities. In FY 2007, FDA will employ resources to advance its mission to protect the public health by assuring the quality of food and medical supplies and by implementing advanced technologies to monitor and speed innovations to market that will make foods safer and medical products more effective, safer, and more affordable. We will also implement advanced tools to ensure that the medical community can use molecular biology to improve outcomes for patients. We must accomplish these goals in a way that provides the public with the accurate, science-based information they need to use food and medicine to improve their health.

Specifically, the President's budget request focuses on six high priority areas, and proposes increases in these targeted activities above the amount provided in fiscal year 2006: \$30.5 million for Pandemic Preparedness, \$19.9 million for Food Defense, \$5.9 million for the Critical Path to Personalized Medicine, \$4.0 million for Human Drug Safety (plus an additional \$0.7 million in user fees), \$2.5 million for Human Tissue Safety, and \$7.4 million to meet the statutory triggers of the Animal Drug and Medical Device user fee programs.

FDA also seeks \$20.3 million for inflationary cost of living increases, \$1.2 for the Unified Financial Management System, and an investment of \$14.3 million for the agency's infrastructure needs. To partially offset the cost of these initiatives, the President's budget proposes to strategically redeploy \$52.3 million in base funds. Even in an era of declining budgets, FDA recognizes the need to modernize and transform operations to address the emerging needs of the 21st century. Therefore, we engaged in an ongoing process to strategically redeploy resources to address high-risk public health challenges while maintaining our century-old commitment to principles that have made us the world's "gold standard" for regulating food and medical products. In doing so, the proposed budget will permit FDA to meet its ongoing statutory and regulatory responsibilities, while allowing us to initiate new and expanded efforts in critical areas of our mission. Now I would like to provide you with greater detail on our proposed budget increases.

I. Pandemic Preparedness (+\$30.5 million)

To safeguard Americans from the danger of pandemic influenza, FDA requests a total base program of \$55.3 million in FY 2007. This amount is \$30.5 million more than the FY 2006 enacted level (including the \$20 million in supplemental appropriations provided by P.L. 109-148). With these funds, we will conduct a comprehensive program to prepare for and respond to the risks of a pandemic flu outbreak. The resources in this request will allow FDA to:

- Engage in public-private partnerships to select, prepare, and test pandemic seed strains.

- Develop reagents (used to assess vaccine potency) that are essential for successful large-scale manufacturing.
- Evaluate and license flu vaccines that rely on current technology and promising new approaches (such as cell culture-based vaccines) to permit faster and more efficient vaccine manufacturing.
- Provide essential technical support to vaccine manufacturers throughout the vaccine development process, including support throughout the manufacturing phase.
- Develop analytical methods to detect, identify, and quantify antiviral residues in poultry and take steps to ensure that these drugs are not used in ways that promote drug resistance in humans.
- Develop and validate methods to detect avian influenza in foods and reassure American consumers about how to safely handle and cook these foods.

We make this request because public health experts tell us that the risks of being unprepared for a pandemic could mean the death of up to 200,000 Americans (based on a medium-level pandemic scenario) and economic losses of up to \$160 billion. In the near term, our pandemic initiative will stimulate broader interest among vaccine manufacturers, as they recognize that FDA will provide consistent technical support to overcome vaccine development hurdles. We have already seen results in this area. In the longer term, our FY 2007 investment will yield essential seed strains and reagents, and allow us to transfer this technology to manufacturers, while we also perform our regulatory responsibilities of evaluating and licensing pandemic influenza vaccine products. Over the next 2-4 years, we will also fulfill our public health responsibilities related to foods and veterinary products, by delivering methods to detect antiviral

residues and by educating Americans about safe food practices.

II. Food Defense (+\$20 million)

FDA seeks an investment of an additional \$20 million in FY 2007 to protect the nation's food supply from terrorist attack, by developing and deploying improved methods to screen food and feed imports and expanding the Food Emergency Response Network (FERN).

FERN is a network of federal and state laboratories designed to ensure that we have the analytic surge capacity to respond to an attack on the food system. By the end of FY 2006, we plan to have an operational FERN system of 10 Federal and 10 state labs. The FY 2007 funds (\$13 million) will allow FDA to expand the current network by six additional labs, located at existing state facilities, and we will work to bring these on-line before the end of the fiscal year. We will fully equip these new labs, and provide operational funding and technical assistance so that they can conduct food defense activities. Our technical assistance will include proficiency testing on the new equipment and training to validate their ability to conduct food testing in response to an emergency. The result of this investment will be a more robust and more geographically diverse capability to provide the essential surge capacity to test contaminated food samples and allow us to warn the public about threats to the food supply. By working cooperatively with state facilities, we can stretch our federal dollars and strengthen food defense at the Federal and state level.

Within the \$20 million increase, we will also:

- Conduct food defense research (\$1 million) to fill in gap areas that we identified in the vulnerability assessments we conducted on 23 major food products such as baby food, infant formula, dairy products, soft drinks, and bottled water.
- Strengthen the Electronic Laboratory Exchange Network (eLEXNET), an Internet based data exchange system used by federal, state, and local government food safety laboratories. Using FY 2007 funds, we will use eLEXNET to provide food sector-specific information to sister agencies and build a secure interface so that we can exchange data with DHS. Finally, we will purchase essential reagents and test kits to conduct biomonitoring surveillance. In FY 2007, we will spend \$2 million of the Food Defense increase for these activities.
- Improve our Emergency Operations Network (\$1 million) to allow FDA to conduct more sophisticated incident tracking for food-related emergencies.
- Continue Field support of food defense operations (\$3 million), including the targeting of potentially high-risk imported foods through Prior Notice Import Security Reviews based on intelligence, FDA inspection reports, discrepancies in prior notice reporting and sample collection and analysis.

III. Critical Path to Personalized Medicine (+5.9 million)

FDA requests an increase of \$5.9 million in FY 2007 for the Critical Path to Personalized Medicine Initiative. This will allow us to increase the predictability and efficiency of developing

new medical products, and deliver greater benefits to patients as we accelerate the field of personalized, predictive, preemptive, and participatory medicine. Our goal is to stimulate a new generation of scientific tools that will enable product sponsors to evaluate and predict the safety and effectiveness of drugs. This will permit physicians to tailor therapies to individual patients and avoid potentially dangerous adverse events. The Critical Path to Personalized Medicine Initiative fulfills the Congress' expectation under the Food and Drug Administration Modernization Act, when it charged FDA to work collaboratively with partners in government, academia, and industry to advance medical product development.

The FY 2007 investment will support:

- **Imaging Initiative** – Our Critical Path investment will support efforts to accelerate an understanding of the use of positron emission tomography (PET) and other advanced imaging technologies as surrogate endpoints for developing new cancer drugs. A surrogate endpoint helps to predict the benefit that a patient may experience from therapy. In FY 2007, we will participate in developing technical standards for PET imaging – the tools that will enable drug developers to evaluate and improve the effectiveness of new products.
- **Improving Stent Design** – Cardiovascular disease is a significant cause of morbidity and mortality in the U.S., and drug eluting stents have become a standard therapy to address cardiac disease in many patients. Today, most vascular stents eventually fail and alternative designs are difficult to test in humans. Our objective is to improve stent performance and safety by predicting and avoiding product failures. In FY 2007, we will develop the preliminary components of a simulation model of drug eluting stent behavior

in adults and children. Also in FY 2007, we will work to develop open source imaging software to assess stent performance and begin to develop guidance for industry on using the simulation model to predict stent performance.

- ECG Warehouse – We will invest funds to develop the tools to permit searches of electrocardiogram (ECG) data submitted with drug applications so that we can identify cardiovascular risk patterns associated with unsafe drugs. We will also partner with academia and the public sector in FY 2007 to conduct additional ECG analyses. This will improve our ability to identify cardiac safety concerns before we approve a drug for marketing and also detect post market safety signals. Through these activities, we will help ensure that therapies are safe and effective, and we will improve outcomes for patients who are using products that are already on the market.

The need for new medical treatments and the investment of billions of dollars in basic biomedical research led many in the medical community to anticipate a new wave of medical products capable of dramatically saving and extending lives. Yet the recent slowdown in the rate of new medical treatments actually reaching patients is a significant concern at FDA. Products fail before they reach the market because clinical trials fail to demonstrate safety or efficacy, or they cannot be manufactured at a consistently high quality. Despite recent innovations, many serious and life-threatening diseases still lack effective treatments.

At FDA, we witness the full spectrum of drug, device, and biologic product development. From this unique perspective, it is clear that the development of evaluative scientific tools to utilize in

medical product development has not kept pace with the rapid advances in basic sciences. The path from cutting-edge medical discovery to the delivery of safe and effective treatments is long, arduous, and uncertain – and it does not yield extensive information on product performance. To correct this imbalance, FDA initiated the Critical Path to Personalized Medicine, a program designed to modernize medical product development to ensure more efficient and more informative product development and clinical use. FDA considers the Critical Path Initiative to be its top scientific policy initiative for at least the next five years.

FDA's Critical Path Initiative will stimulate research community efforts to identify the essential biomarkers and improved clinical trial designs that will accelerate product development.

Biomarkers are measurable characteristics that reflect physiological or disease processes.

Medicine can use biomarkers to predict or monitor response to therapy. The initiative will

generate essential information to identify patients likely to benefit from a treatment and patients

more likely to respond adversely to a product. Without clinically proven biomarkers and

innovative trial designs, we cannot modernize medical product development and realize the

potential of personalized medicine. The subcommittee recognized this need when it appropriated

funds for FDA in fiscal year 2006 to study cardiovascular biomarkers predictive of safety and

clinical outcomes, and the funds that we request in FY 2007 will support broader efforts to

achieve personalized medicine.

IV. Drug Safety (+4.7 million in budget authority and user fees)

FDA will build on recent improvements to its drug safety activities with an FY 2007 increase of

\$4.7 million (a \$3.96 million increase in budget authority and \$0.74 million in PDUFA user fees). The proposed FY 2007 budget will provide a significant increase to our base resources for drug safety and will allow FDA to continue to strengthen our capacity to recognize and act on emerging drug safety concerns.

As we plan for fiscal year 2007, we must continue to focus on the needs of the patient. We must constantly ask ourselves – how can we achieve the proper risk/benefit balance while speeding patient access to safe and effective products? U.S. pharmacies fill approximately 3.7 billion prescriptions per year and consumers make more than 5 billion over-the-counter drug purchases annually. The effect of these medicines on the full spectrum of our population causes unforeseen problems to surface that may not have appeared during the sometimes-lengthy drug review process.

Our FY 2007 drug safety request will permit us to launch a web-based system that provides agency analysts faster access to adverse event reports. Known as AERS II, this system will allow FDA to more easily evaluate potential safety issues, and improve our ability to take follow-up actions to protect patients. FY 2007 funding will also allow us to analyze valuable drug safety information housed in CMS and other population-based databases and to conduct studies of high priority safety issues in the Medicare population. Studies conducted on these types of databases will provide more supporting evidence about drug use under a broader range of conditions, and more detailed evidence about drug safety in subgroups of patients, such as the elderly, and in patients with multiple medical conditions. This will provide FDA with many of

the tools necessary to formulate and communicate safety information to health care practitioners, consumers, and the research community in a more timely and user-friendly way.

We have made important drug safety enhancements during the past year, and I would like to highlight these activities for your now. The members of this Subcommittee provided an increase of \$9.9 million in FDA's FY 2006 budget. We will bolster premarket and postmarket drug safety functions by using these funds to:

- Increase the professional staff in FDA's Center for Drug Evaluation and Research (CDER) who perform high priority drug safety reviews.
- Increase the number of staff with expertise in critical areas, such as risk management, risk communication, and epidemiology.
- Expand our information technology infrastructure for monitoring post-marketing data by increasing access to a wide range of clinical, pharmacy, and administrative databases.
- Hire additional experts to enhance use of multidisciplinary, multi-office teams to interpret drug safety data.
- Access external population-based "linked" databases to identify drug safety signals.

Other important drug safety accomplishments during the past year include:

- Establishing a Drug Safety Oversight Board to provide independent oversight and advice on drug safety and disseminating safety information.

- Appointing a new director of CDER's Office of Drug Safety.
- Conducting a public meeting of experts to assess risk communication about drugs and to plan future communication efforts.
- Unveiling a major revision to the format of prescription drug information, commonly called the package insert, to give healthcare professionals clear and concise prescribing information.

These efforts emphasize our commitment to providing the American public with safe and effective medical products.

V. Tissue Safety (+\$2.5 million)

FDA requests an increase of \$2.5 million to provide the essential resources to support a human tissue safety. These funds will allow the agency to:

- Commence a comprehensive risk-based approach to assure the safety and quality of human cells, tissues and cellular and tissue-based products used for transplantation. Examples include corneas, heart valves, ligaments, joints, skin, or other tissues.
- Promptly monitor and investigate adverse events and tissue product problems.
- Take early action to improve tissue practices and prevent tissue-related injuries and deaths.
- Educate industry, the medical community, and the public about human tissue safety.

- Support promising new technologies that use cells and tissues, including therapies for diseases such as cancer, AIDS, Parkinson's disease, hemophilia, diabetes, and other serious conditions.

This program will provide guidance and predictability to more than 2,000 registered establishments that process and distribute tissue products used in medical procedures that save or enhance the lives of recipients. FDA has seen its workload in the area of human tissue transplants rise dramatically as transplants have increased from approximately 350,000 in 1990, to more than 1,000,000 annually. The number of transplants will continue to rise in the years ahead.

With these resources, FDA will conduct 75 additional tissue inspections in FY 2007 and thereby increase our annual inspection coverage to 325 facilities. Through inspection and monitoring activities, we can ensure that establishments demonstrate safety and efficacy of their products. These funds will also permit FDA to rapidly review, track, and analyze tissue deviation reports. Finally, we will issue guidance for industry on emerging issues relating to the eligibility of donors and good tissue practices. The goal of these efforts is to ensure safe outcomes for patients when they receive tissue transplants.

FDA's announcement in early February that we ordered a New Jersey company to cease operations is evidence that we will take action to protect the public health against tissue

manufacturers that fail to follow safety requirements. This is an example of the targeted enforcement action we will conduct to protect the public health when we have evidence unsafe tissue practices.

VI. Budget Authority in Support of User Fee Programs – MDUFMA and

ADUFA (+\$7.4 million)

To achieve more timely and cost-effective review of new medical devices and animal drugs, we continue to implement Medical Device User Fee and Modernization Act (MDUFMA) and the Animal Drug User Fee Act (ADUFA). Congress enacted these statutes to allow the agency to collect user fees from companies that submit medical device and animal drug applications.

In FY 2007, we are requesting a total increase of \$7.4 million in new budget authority (\$4.9 million for medical devices and \$2.5 million for animal drugs) to ensure that we meet statutory requirements, known as triggers, and fulfill the FY 2007 performance commitments under these programs. If we do not receive sufficient budget authority to meet the statutory triggers, FDA will lose the right to collect \$55.3 million in user fees. The flow of potentially life saving medical devices will decline and the use of unapproved drugs in food-producing animals will likely rise.

Under both these user fee programs, we pursue a complex and comprehensive set of product

review goals. Each year brings additional goals, and the goals become more aggressive. FDA provides a complete report on its performance on under these programs at the end of each year.

The proposed increase will permit FDA to maintain its highly skilled scientific and professional review staff and conduct speedier review and approval of safe and effective medical devices.

Under MDUFMA, FDA is meeting, or is on track to meet, nearly all of the performance goals for FY 2003, FY 2004, and FY 2005. We will continue to make program improvements to ensure we meet the goals for FY 2006 and FY 2007. Under ADUFA, FDA expects to meet or exceed all performance goals.

VII. Cost of Living – Paying our People (+20.3 million)

Soon after the President appointed me Acting Commissioner, I told my FDA colleagues that the well-being of our agency's employees was one of my top priorities. The talented and dedicated FDA employees are the most important reason for our Agency's success.

The proposed increase of \$20.3 million to meet inflationary pay costs is essential to FDA's ability to accomplish its public health mission. Payroll costs account for more than sixty-percent of the FDA budget, and the Agency is not able to absorb inflationary increases on such a significant portion of its resources. To meet this need, the agency requests an increase of \$20.3 million. These funds will allow FDA to maintain its world-class workforce and achieve the promise of a healthier America.

FDA's diverse portfolio of public health responsibilities demands that we maintain a large cadre of scientists and professionals with the training and experience to respond to complex and escalating public health challenges. This workforce is directly engaged in both developing the science of regulation as well as administering regulatory functions.

FDA professionals are increasingly challenged by evolving food defense responsibilities as well as growing responsibilities in regulation of vaccine, drug, and device, development. Within the past year, they have addressed threats such as BSE (Mad Cow Disease), Salmonella, West Nile Virus, and pandemic flu. The FDA workforce reviews, approves, and continues to ensure the safety and effectiveness of products to manage cancer, diabetes, and heart disease, as well as oversee products intended to preserve health. FDA principally expends its budget for payroll that allows us to recruit and retain a skilled workforce dedicated to safeguarding the public using advanced tools to preempt public health threats.

VIII. Unified Financial Management System (UFMS) (+\$1.2 million)

In fiscal year 2007, FDA seeks an increase of \$1.2 million to fully utilize the Unified Financial Management System (UFMS) for all of our financial transactions. These funds will allow FDA to achieve a major program milestone in the implementation of a new centralized financial management system under the Department of Health and Human Services (HHS). These additional funds would bring the fiscal year funding level to \$14.1 million.

UFMS is changing the way HHS agencies do business as it improves efficiencies in business processes and technology. It will replace five redundant and outdated accounting systems in use at the National Institutes of Health, the FDA, the CDC, the Centers for Medicare and Medicaid Services, and the DHHS Program Support Center. The requested increase and the base funds in our budget will support dual functions. First, as a component of the Department-wide system, FDA resources will support testing and integration of the UFMS system, as well as regular operation and maintenance of UFMS. Second, FY 2007 funding will support FDA-specific functions such as the purchase of reporting tools and software licenses, essential system upgrades and new software releases, and training to support FDA users of this new system. This will ensure that we satisfy financial requirements and provide timely financial information to executives and managers to support better decision making. As FDA fully integrates UFMS into our systems and way of doing business throughout FY 2007, we expect to witness the projected efficiencies for this vital enterprise and will be able to use UFMS' full financial management capability.

IX. Infrastructure (+\$11.3 million)

In FY 2007, FDA submits a modest request to fund three fundamental components of our physical infrastructure:

- An increase of \$10.5 million for rent payments to the General Services Administration (GSA).
- An increase of \$3.8 million in budget authority to maintain progress on the White Oak Consolidation project.

- A reduction of nearly \$3 million below the fiscal year 2006 appropriated level for our Buildings and Facilities account.

In total, these proposals would result in a net increase of \$11.3 million for FY 2007.

We also plan to commit \$8.2 million in PDUFA carryover funds to the White Oak project and \$1.9 million for GSA rental payments. FDA continues to seek support for the White Oak project with the goal of eventually housing over 7,700 staff in 2.3 million square feet of space. As of the end of calendar year 2005, we have approximately 1,850 staff on site at White Oak, in three buildings with almost 700,000 square feet. The new buildings will eventually replace all 40 existing, fragmented facilities in 16 locations that support the Office of the Commissioner, and all of our Centers and the Field headquarters, other than the Center for Food Safety and Applied Nutrition and the National Center for Toxicological Research.

X. Proposed User Fees: Reinspection and Food/Animal Drug Export

Certificates (\$25.5 million)

In addition to those user fees authorized by statute, the FDA is proposing two new user fees. The first, estimated at \$22.0 million, would pay the full cost of reinspection and other FDA follow-up work if a manufacturer fails to meet important FDA requirements such as Good Manufacturing Practices, which help ensure high quality and safety of FDA regulated products. When a firm fails an inspection, FDA must conduct a reinspection and perform associated laboratory analysis to verify the firm's corrective measures.

The reinspection user fee will ensure that facilities that fail to comply with established health and safety standards bear the cost of FDA follow-up inspection. We are asking Congress to assess the cost of follow-up inspections on those who fail to comply, rather than on the American taxpayer, who bears the cost today. The natural consequence of this change will be that manufacturers will work to ensure that they meet established standards.

The second proposed new user fee will cover the cost of issuing an approximately 37,000 food and animal feed export certificates. We have estimated the cost of this user fee program at \$3.5 million. Although the agency's effort to issue these certificates benefits industry exports, FDA must support this function at the cost of other vital public health activities. FDA's proposal for user fees would establish a source of dedicated funding for this activity and allow the agency to better perform this function. The domestic food and animal feed industry would benefit from the agency's enhanced ability to facilitate the exportation of their products.

The Federal Food, Drug, and Cosmetic Act (the Act) authorizes FDA to collect user fees for export certificates for human drugs, animal drugs, and devices. However, this authority does not extend to collecting user fees for export certificates for foods and animal feed. FDA expends significant resources annually to issue these certificates, and the agency needs to focus its resources on activities that are central to its public health mission. The Administration has asked that Congress fund these two user fee programs with mandatory budget authority.

XI. Current Law User Fees (+20.2 million)

We are also requesting an increase of \$20.2 million for user fees that support prescription drug review, medical device review, animal drug review, mammography inspections, export certification, and color certification fees, for a total FY 2007 user fee level of \$402 million.

These fees enable FDA to review medical products in a timely manner and reimburse FDA for two services (color certification and export certification for human drugs, animal drugs, and devices) that we provide to industry. All of these requested fee increases are authorized under current law. In FY 2007, FDA will work with Congress on the reauthorization of the PDUFA, MDUFA, and ADUFA user fee programs.

Closing

FDA's program level request of \$1.95 billion is necessary to perform our mission – established by Congress – to protect and promote the health and safety of the American public. At the Food and Drug Administration, we work tirelessly to fulfill these public health responsibilities. Our goal is to maximize the benefits and minimize the risks from the products we regulate.

Among my highest priorities as Acting Commissioner – for as long I am privileged to serve at the helm of FDA – will be to foster the development of the FDA of the 21st Century. Building on the success of the past, we will maintain our “covenant of trust” with patients and the public. We will assure they have safe, effective, modern, and cost efficient solutions for the challenges to their health and well-being, and the health and well being of their children and grandchildren.